

Patient information sheet:

Project title: Low dose of oral steroids in the treatment of otitis externa (swimmer's ear)

You are invited to take part in a research project about otitis externa, commonly known as swimmer's ear. The purpose of the study is to trial a new treatment for swimmer's ear. The study is being conducted by Associate Professor Ronny Gunnarsson at School of Medicine & Dentistry, James Cook University, Dr Graeme Balch at Toogood Rd Medical Centre and co-workers.

A. Reasons for study

Otitis externa, commonly known as "tropical ear", "surfers ear" or "swimmers ear", is a frequent problem worldwide, especially in the tropics. The pain and swelling often makes proper topical treatment (ear drops or similar) difficult.

Although scientifically unproven, some GPs use oral corticosteroids (cortisone). This procedure is not officially recognised. This research project is investigating the effect oral prednisolone (a corticosteroid with anti-inflammatory properties) has on the treatment of painful otitis externa. Some GP's have long believed prednisolone is of substantial help to patients in pain from this condition in addition to their usual treatment which can include: ear cleaning, ear drops and oral antibiotics. They think prednisolone relieves pain in the ear and other symptoms much more quickly than the usual treatment, resulting in a faster cure. However, to date there are no scientific studies confirming this belief.

If this study cannot show a benefit then doctors already using this treatment will be encouraged to cease or, if it is shown to be helpful, then it may be used more confidently by all doctors treating this condition.

B. Your participation

This is a clinical trial and participants will be divided into two groups. One group will be given active tablets and the other group will be given a placebo tablet as an addition to conventional treatment. Participants will not know to which group they have been allocated. Some details from your doctor's consultation will also form part of the study.

If you agree to be involved in the study, you will be asked to take one "study tablet" every 12 hours (in total 8 tablets), along with the treatment your Doctor prescribes. You will also be asked to complete a daily diary about your symptoms, your level of pain, and how this is affecting your daily activities. When you have no further symptoms, you will be asked to complete a final questionnaire and return it with your diary to the researchers. The diary should take about 2-3 minutes every day and the final questionnaire should take about 10 minutes to complete.

Taking part in this study is completely voluntary and you can stop taking part in the study at any time without explanation or prejudice. Choosing not to participate or withdrawing from the study will not affect your future care and treatment in any way.

As with any treatment, there are possible risks. Although you will still be prescribed the usual treatment for swimmer's ear, there is a possibility that your symptoms may get worse e.g. you may experience increased pain or a fever. If this occurs, you should immediately go back to your GP, or if this GP is unavailable attend another GP or the emergency department of the nearest hospital. Furthermore, you should immediately stop taking the "study tablets".

Your responses and personal details will be strictly confidential. Your responses will be allocated a code as an identifier and the codes will be stored separately from your responses to ensure confidentiality. The data from the study will be used in research publications and reports. You will not be identified in any way in these publications.

C. Contacts

If you choose to participate then we will try to contact you by phone, text or e-mail within 72 hours after you got the study tablet to hear if you have any questions regarding the study. We will also try to contact you if we don't receive your diary and the final questionnaire within 2-3 weeks after you accepted to participate. If you have any questions about the study, please contact Dr Graeme Balch.

Principal Investigators:

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If you have any concerns regarding the ethical conduct of the study, please contact:
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